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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,878	11/21/2005	Hiroshi Takahashi	0760-0346PUS1	9660
2292	7590	11/15/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			GODDARD, LAURA B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/533,878

Applicant(s)

TAKAHASHI ET AL.

Examiner

Laura B. Goddard, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/5/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Election filed August 28, 2006 in response to the Office Action of July 28, 2006 is acknowledged. Applicant elected with traverse Group I, claims 1-7 and 10.

Applicants argue that the cited references (Park et al (J Cancer Res Clin Oncol, 2001, 127:489-494) and Takahashi et al (Cancer Research, 1988, 48:6573-9, abstract only), considered either individually or in combination do not disclose or suggest each and every limitation of the presently claimed invention. Applicants argue that the disclosure of Park et al discuss using model cells which are grown in tissue culture for the ultimate purpose of performing RT-PCR on the DNA of the cells isolated, however, claim 1 is directed to binding cancer cells which have been separated from the body (p. 7).

The argument has been considered but is not found persuasive because Applicants are arguing limitations not recited in the claims. Park et al teach SNUC4 human colon cancer cells contained in blood. The colon cancer cells are cells separated from a human body, hence the limitations of the claims are met and Examiner has established a *prima facie* case of obviousness. For these reasons, the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-10 are pending. Claims 8 and 9 are canceled. Claims 1-7 and 10 are currently under prosecution.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see p. 11, line 3). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "**the body**". There is insufficient antecedent basis for this limitation in the claim.

4. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: examining steps. It is unclear what is begin examined in the cancer cells.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5, 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (J Cancer Res Clin Oncol, 2001, 127:489-494) and Takahashi et al (Cancer Research, 1988, 48:6573-9).

The claims are drawn to a method for examining cancer cells comprising binding cancer cells separated from the body, which cells express SF-25 antigen on their surfaces, to magnetic beads utilizing antigen-antibody reaction between said cancer cells and an anti-SF-25 antibody or antigen-binding fragment thereof, then collecting said magnetic beads by magnetic force, and examining said cancer cells bound to magnetic beads (claims 1 and 2), wherein said cancer cells are those contained in blood (claims 3 and 10), wherein said cancer cells are colon cancer cells (claims 4 and 5), wherein the examination is of nucleic acids (claim 7).

Park et al teach immunomagnetic beads coated with an antibody specific for a cancer antigen expressed by cancer cells and using said immunomagnetic beads for the separation and isolation of said cancer cells that express the antigen and examining the isolated cancer cells using RT-PCR (abstract, p. 490, col. 1 and 2). The cancer cells were separated from a human body and contained in blood (abstract; p. 490, col. 2). Park et al teach that immunomagnetic bead selection successfully isolates and concentrates cancer cells expressing the antigen recognized by the antibody comprised by the bead, provides a more sensitive method for RT-PCR analysis than regular RT-PCR, and decreases chances of false positives in RT-PCR analysis (p. 493, col. 1). The

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immunobead RT-PCR assay relies on a preliminary isolation of tumor cells from body fluids, which is then followed by amplification of one or more mRNA markers by RT-PCR (p. 493, col. 1). Park et al teach that the feasibility and the prognostic value of immunobead RT-PCR assay, which combines the enrichment of cancer cells by immunomagnetic bead selection and the RT-PCR amplification of tumor-specific mRNAs, has been demonstrated in several studies of breast, prostate, and gastrointestinal cancers (p. 492, col. 2). Park et al does not teach using SF-25 antibody.

Takahashi et al teach monoclonal antibody SF-25 that binds SF-25 antigen expressed by cancer cells. Takashi et al teach that SF-25 antibody is useful for distinguishing between normal colon and cancerous cells, hence the antibody selectively binds to cancer cells expressing SF-25 antigen (abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make and use an immunomagnetic bead comprising antibody SF-25 antibody because immunomagnetic beads comprising antibodies used to isolate different cancer cells are well-known in the art as taught by Park et al. One would have been motivated to use an immunomagnetic bead comprising antibody SF-25 in order to successfully isolate and concentrate colon cancer or cancer cells expressing SF-25 antigen in order to increase sensitivity of analysis of the cells.

6. **Conclusion:** No claim is allowed.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.
Examiner
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JEFFREY SIEW
SUPERVISORY PATENT EXAMINER